Evaluation of a Capacitively-Coupled, Non-Contact (through Clothing) Electrode or ECG Monitoring and Life Signs Detection for the Objective Force Warfighter

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ABSTRACT

A new device that measures ECG inter-beat intervals through clothing is described and compared to a resistive contact electrode. The capacitively coupled non-contact electrode (CCNE) underwent a 40 person human trial at the Walter Reed Army Institute of Research this past year. This sensor can detect ECG and respiratory signals thru clothing and is being considered by the US Army as a physiological monitoring detection sensor on the Objective WarFighter uniform of the future. In this study, three CCNE sensors were compared to an FDA-approved monitor (3-lead) using contact electrodes to determine if the R-R inter-beat intervals of the two methods were "the same" or not. Results of the "at rest in supine position" for determining heart rate based on inter-beat intervals of the ECG are presented. The test results indicate that, relative to the ECG contact electrode, the CCNE sensors work for determining R-R inter-beat intervals reliably. Test subject variability in the different weight categories indicates similarity between the two types of electrodes and statistics for comparison are presented. The CCNE sensor gives "unbiased" estimates (116 out of 117 difference signals gave "unbiased" estimates). The CCNE sensor gave close estimates of the inter-beat intervals in 30 out of 39 test subjects with less than 14 ms differences. The CCNE difference signals give statistically "similar" results within each test subject (37 out of 39 test subjects had statistically similar results). Females showed more variability than males for each weight class. Males and females in weight class 5 had the largest measures of variability.

Material has been reviewed by the Walter Reed Army Institute of Research. There is no objection to its presentation and/or publication. The views of the authors do not purport to reflect the position of the Department of the Army or the Department of Defense, (para 4-3), AR 360.5.

INTRODUCTION

Biopotential sensors can generally be categorized as invasive or non-invasive. Invasive sensors are implanted surgically and are used for isolation of specific potential sources in the brain or the peripheral nervous system. Non-invasive sensors are referred to as surface, skin, or scalp electrodes or sensors, and are applied to the skin surface. To ensure a good resistive contact to the test subject, such electrodes typically utilize a conducting electrolyte or gel and are hence often referred to as wet electrodes. Such electrodes are the standard method used in clinical and research applications.

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Various attempts have been made to overcome the limitations of wet electrode technology for measuring bioelectric signals such as ECG and EEG on the human body. Advances include one class of surface electrodes that does not use electrolytes. These electrodes are referred to as active electrodes and employ an impedance transformation at the sensing site via active electronics. Active electrodes are subdivided into two types—dry electrodes, which rely on a metallic surface in direct contact to the test subject that uses a combination of resistive and capacitive coupling to the local skin potential, and insulated electrodes, which utilize only capacitive coupling.

Detection of human body bioelectric signals using purely capacitive coupling was first reported in 1968 [1]. A schematic for a capacitive electrode system, comprised of two conducting plates placed close to the body and connected to the input of a differential amplifier, is shown in Figure 1**.** The plates have a capacitance, C_b, to the region of the body in the immediate vicinity of the plates, and a capacitance C_f, to the free space electric potential. C_f represents the capacitance to the source via all other paths except the paths close to the plate.

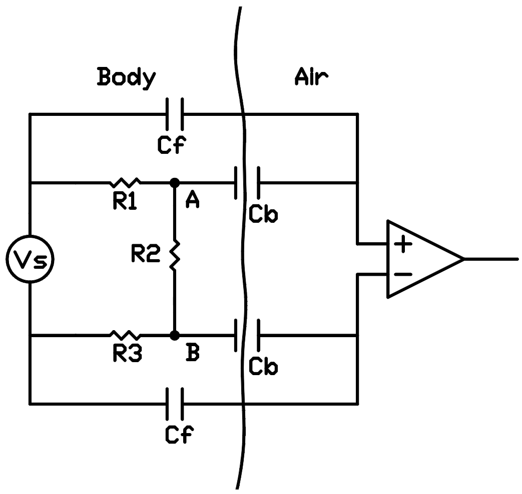

Figure 1: Approximate Equivalent Circuit for Capacitive Coupling to the Human Body

For prior capacitive electrodes, C_b had to be high—typically 1 nF to 100 nF. C_b is approximately given by the standard expression for a parallel plate capacitor, and is thus inversely proportional to the spacing between the electrode and the body [2,3]. This dependence is so sensitive that if the electrode moves from being on the surface of the skin to just 100 μm away, C_b changes by approximately a factor of 10. Thus, even though they do not require direct resistive contact to the body, traditional capacitive (insulated) bioelectrodes are very susceptible to displacement.

In 2001, researchers at Quantum Applied Science and Research (QUASAR) developed a new class of sensor that measures the electric potential in free space, i.e. without physical contact to any object. It was observed that the sensors were able to measure the ECG of a fully clothed person standing within a range of about 10 inches. (Patent Pending) In 2002 QUASAR developed a compact version of the sensor, termed the capacitively-coupled noncontact electrode (CCNE), specifically to measure ECG through clothing (See Figure 2) This first version of the ECG electrode, including all amplification electronics, is approximately 1 inch square with thickness of 0.35 inches.

This report describes the results of the first human trial of this new electrode technology. The goal was to compare the CCNE operating through regular clothing with a conventional 3-lead ECG using resistive electrodes for the purpose of measuring interbeat intervals.

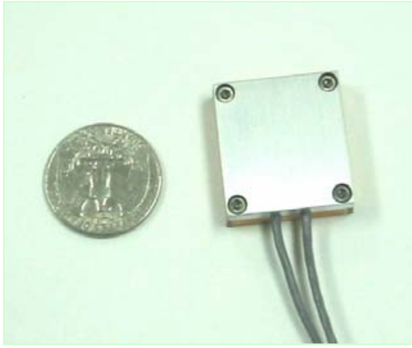

Figure 2: Capacitively Coupled Noncontact Electrode used in this Study

The principal application envisioned for the technology is continuous readout of ECG of military personnel as part of the Objective Force Warrior (OFW) soldier uniform. OFW is the Army's flagship Science and Technology initiative to develop and demonstrate revolutionary capabilities for Objective Force soldier systems. Including physiological monitoring such as ECG in the Objective Force Warrior and Land Warrior systems is of great interest to the Army. It is widely known that there are many problems associated with contact electrodes for long-term ECG monitoring, including loss of contact to the test subject due to drying of application glue or environmental factors (e.g. rain) and test subject resistance to wearing the electrodes due to discomfort caused by factors such as skin irritation. Therefore, a non-contact system would be of great benefit to the Army.

It has been observed that 90% of combat fatalities during conventional warfare occur forward of the battalion aid station (BAS), the first organized medical treatment facility, and that two-thirds of these fatal injuries involve significant hemorrhage [4]. Furthermore, about 60% of these deaths occur within the first 10 to 15 minutes after injury. These statistics underscore the importance of the Army's equipping their medics with the capability to rapidly locate, assess, and effectively treat the wounded. It is estimated that about 25% of these casualties might be salvageable with prompt hemostasis**,** and some degree of fluid resuscitation to sustain them until definitive surgery and resuscitation can be achieved in the later phases of their care [5]. Since the medic carries so little resuscitation fluid (only enough to replace a 15% blood loss) and he has to often deal with many potential casualties at once, he must use his resuscitation resources judiciously, deciding when and how much fluid should be given. The medic will need reliable physiological monitoring that is already on the soldier. A non-contact based system would easily be integrated into the OFW program and provide the foundation for operational and combat medic medicine. The information provided by such a system would be helpful to the combat medic to properly ascertain the level of injury and survival potential of the injured, and provide optimum care in the battlefield.

Methods and Materials:

The WRAIR Clinical Trials Division solicited test subjects for 5 weight groups of 4 test subjects each; one set of the 5 groups was to be females and another set males, for a total of 40 test subjects. The inclusion criteria were that they be healthy males and females with no known heart defects, who ranged in weight from 101->173 lbs for females, and 124->220 lbs for males. This sampling represents the majority of the men and women in the Armed Forces today. Table 1 shows the different weight groups is as follows:

Inclusion: Healthy Men/Women with no known cardiac defects, Civilian/Military, ages 18-50, Weight- female: 101-->173 lbs or greater; male: 124-->220 lbs or greater

Table 1

The groups for women are:

101-119 lbs.	4 test subjects
120-137 lbs.	4 test subjects
138-155 lbs.	4 test subjects
156-173 lbs.	4 test subjects
and greater than 173 lbs.	4 test subjects

The groups for men are:

124-147 lbs.	4 test subjects
148-172 lbs.	4 test subjects
173-196 lbs.	4 test subjects
197-220 lbs.	4 test subjects
and greater than 220 lbs.	4 test subjects

A pilot study using two test subjects determined that the best placement for this initial trial was sensors placed 4 inches below the right and left nipples, and one on the left rear shoulder plate transverse with the other two sensors. [6] Because the data acquisition system and test subject were separated by about 6 feet, a ground strap was attached to the right wrist to minimize DC potential differences. This ground strap has been eliminated in the latest iteration of the technology. The three CCNE sensors were held in place with a commercially available Velcro strap (see Figure 3) to hold the sensors to the body over a cotton T-shirt provided by the study. (see Figure 4).

Each sensor detects the local electric potential. As for all such situations, the potential must be measured relative to another voltage. For conventional electrodes the reference voltage is usually obtained by resistive connection to one or more limbs. The goal of the CCNE approach is to operate through clothing without a resistive electrical contact to the test subject. Accordingly, the output of each CCNE electrode was recorded relative to one of the other CCNE electrodes giving a total of three purely capacitive difference signals, i.e.: channel 1 – channel 2 (X0-X1), channel 1 – channel 3 (X0-X2), and channel 2 – channel 3 (X1-X2).

Figure 3: Arrangement of Sensors on Strap

Figure 4: Quasar Employee Wearing the T-Shirt and Velcro Strap

Each test subject was connected to an ECG monitor, pulse oximeter, and blood pressure cuff. An FDA approved clinical ECG monitor BCI Model #3404-001 AutoCorr Plus was used to provide the "gold standard" reference ECG waveforms for all comparisons with the CCNE waveforms. The frontal plane configuration for the 3-lead ECG was used to take resistive measurements [7] with the 3 contact electrodes placed on the right/left chest and lower abdomen. The AutoCorr has an analog output capability to use as comparison to the CCNE. A pulse oximeter was placed on the right hand of the test subject and blood pressure was taken at the beginning of the experiment.

All test subjects were provided with the same make T-shirt to wear during the test in small, medium, large, extra large, and extra-extra large sizes. This shirt was made of 100% cotton to reduce static charge buildup on the body of the test subject. This provided a consistent thickness through which to record all CCNE measurements across the test population.

The test equipment was connected to a data acquisition system using a Measurement Computing PC Card connected to a Laptop computer running Labview. The data were sampled at 500 Hz and stored digitally on the laptop, which was running on battery power. The data were filtered through anti-aliasing band-pass filter amplifiers using 2-35 Hertz. This eliminated interfering radio-frequency interference noise that would have caused trouble for interbeat analysis centered around 17 Hz. Everything was battery powered to provide safety to the test subject. The CCNE provided leakage current resistance to provide protection to the test subject as well. The test subject was put into the supine position and data were taken for 1 minute with normal breathing.

Results:

The data obtained from the study were post-processed using Matlab. A peak-finding algorithm was applied to detect the peak R wave of the ECG in each of the waveforms and the time between two consecutive peaks calculated in milliseconds. The resulting interbeat interval was used to compare the CCNE with the ECG contact electrodes. The raw waveforms for one test subject are shown in Figure 5. This figure indicates that the waveforms are very similar in nature for this individual; this result is typical of most of the test subjects.

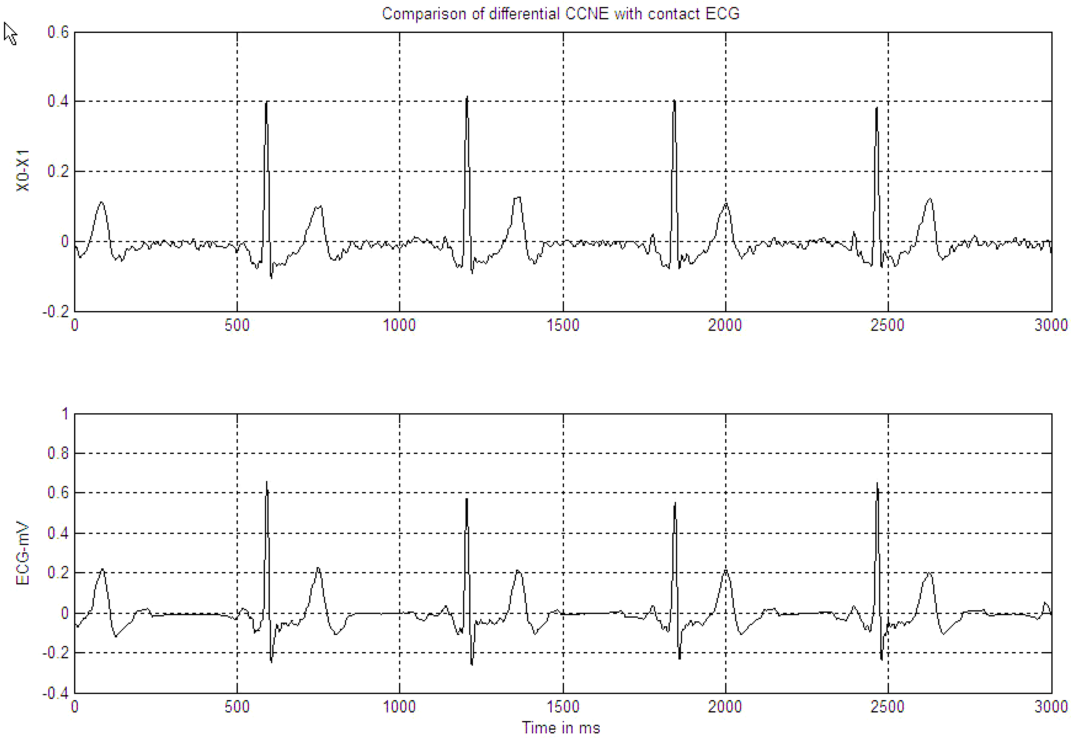

Figure 5: CCNE Difference Signals Compared with Contact ECG Electrodes

The interbeat intervals were calculated using a Matlab Script for peak detection based on the R wave of the ECG for the contact electrodes and the CCNE. A typical result for one test subject using this analysis is in Figure 6. This shows that the interbeat intervals from the CCNE and ECG look identical upon inspection.

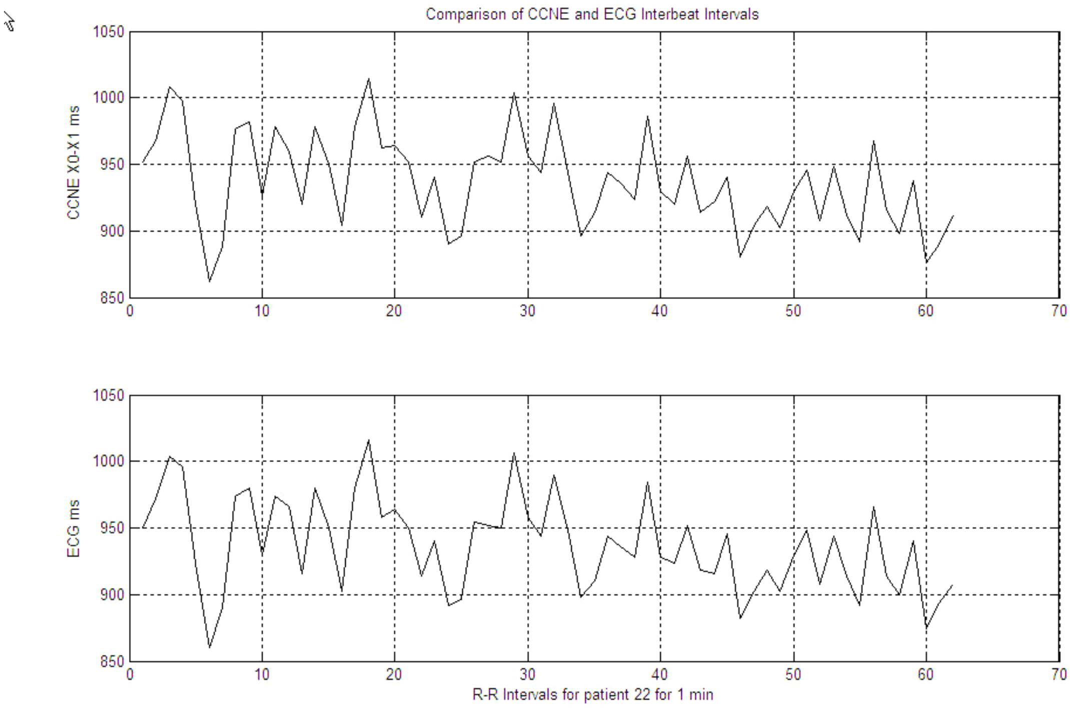

Figure 6: Comparison of R-R Interbeat Intervals of CCNE and ECG Electrodes for 1 min.

Pearson's correlation for each test subject was performed between the CCNE difference signals and the interbeat intervals obtained from the ECG contact electrodes. The results from the correlation are shown in Figure 7. We can see from these results that there is a high degree of correlation between the difference signals of a pair of CCNE electrodes and the ECG contact electrodes. The coefficient of variation was calculated and that is shown in Figure 8. This figure indicates that relative variability (measured by the coefficient of variation) for each subject is nearly identical for the CCNE and ECG contact electrode signals.

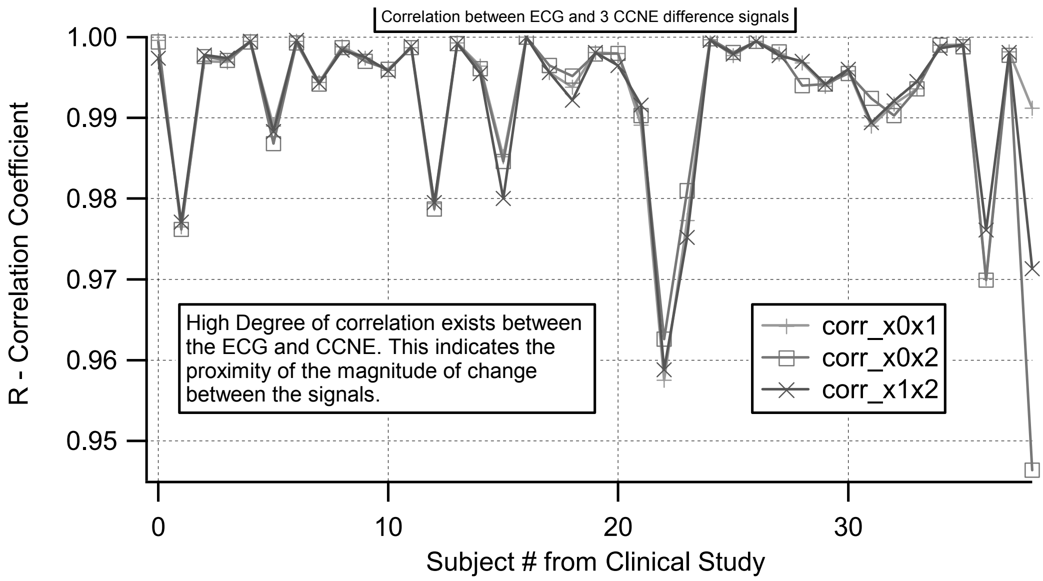

Figure 7: Correlation Between Difference Signals of CCNE with ECG Contact Electrodes

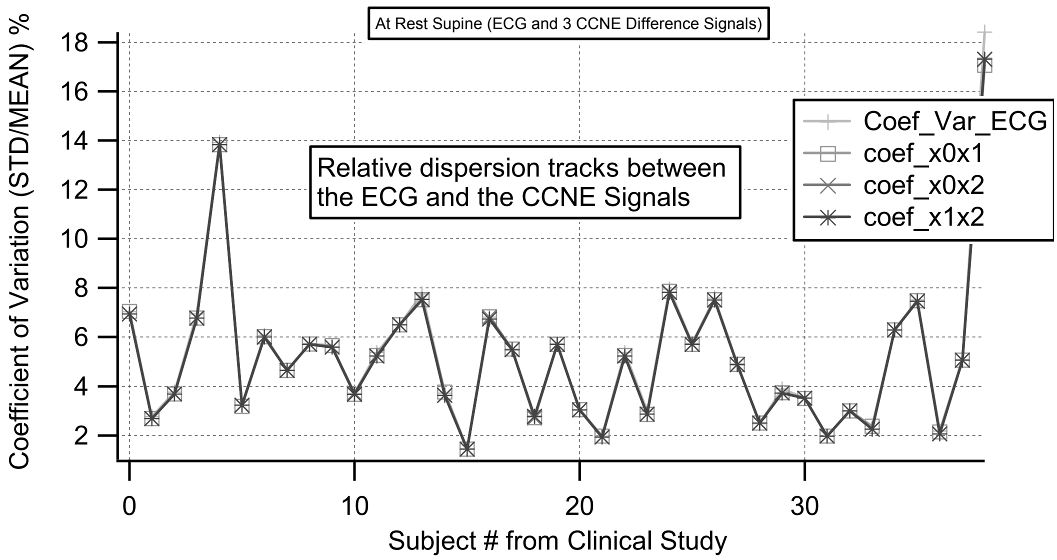

Figure 8: Coefficient of Variation for difference signals of CCNE and ECG contact electrodes ((standard deviation/mean) x 100)

Figure 7 shows that there is a high degree of correlation between the CCNE and ECG contact electrode interbeat intervals. The correlation between the CCNE and ECG intervals suggests that the two sets of intervals might be almost identical, but a high correlation does not exclude the possibility that the CCNE intervals are biased (i.e. CCNE intervals might be consistently higher or lower than the corresponding ECG intervals). To determine whether the CCNE intervals were almost identical to the "gold standard" ECG intervals, two properties of the CCNE intervals were examined. The two inspected properties were "bias" and "closeness"(distance of CCNE intervals from the ECG intervals). Difference scores (i.e. difference signal measurement minus the corresponding ECG measurement) were examined. Results showed that two of the three CCNE difference signals, X0-X2 and X1-X2, gave unbiased estimates for all 39 test subjects, and the CCNE difference signal X0-X1 gave unbiased estimates in 38 out of 39 test subjects (test subject 8 was removed from the study due to data acquisition problems with that test subject). It was noted that the only biased estimate came from subjects 24 and 34 (females in weight class 5).

To indicate the closeness of the CCNE difference signal interbeat intervals to the ECG contact electrodes' interbeat intervals, the absolute value of the differences between the difference signal Xi-Xj interbeat interval (ms) and the corresponding ECG contact electrodes' interbeat interval (in milliseconds) was examined. Results showed that 20 out of 39 test subjects had all CCNE difference signal interbeat intervals within 10 milliseconds of the corresponding ECG contact electrodes' interbeat interval and 30 out of 39 test subjects had all CCNE difference signal interbeat intervals within 14 milliseconds of the ECG contact electrodes' interval. It was noted that 3 of the 9 test subjects with absolute differences exceeding 14 milliseconds were females in weight class 5.

To determine if the three CCNE difference signals gave similar results for each test subject, the proportion of positive, negative, and zero difference scores were examined for each test subject. A chi-square test with 4 degrees of freedom for homogeneous proportions for (3-by-3) contingency tables was calculated. Results showed that 37 out of 39 test subjects had difference signals giving similar results. It was noted that the only two test subjects (24 and) having dissimilar results were both females in weight class 5.

To determine if test subjects in the same gender/weight category had similar results, and to calculate a relative measure of variability among test subjects in each of the 10 gender/weight categories, the proportion of positive, negative, and zero difference scores (defined above) was examined for each of the 10 gender/weight categories (i.e. 10 contingency tables were examined). A chi-square test with 6 degrees of freedom, (except for males in weight class 1 for which the test had 4 degrees of freedom) for homogeneous proportions was calculated. Except for test subjects 24 and 34, the data for each test subject were obtained by averaging over the three difference signals. The pooling of the three difference signals is justified by the results indicated above. Results showed that test subjects in the same gender/weight category gave statistically different results except for males and females in weight classes 1 and 4. Other results shown were: 1) within each weight class, females showed more variability than males, 2) males and females in weight class 5 showed the largest relative measures of variability (i.e. had the largest chi-square values), and 3) within each gender, weight class 1 showed the smallest relative measures of variability.

Discussion / Conclusion:

Although resistive contact electrodes for measurement of ECG are the gold standard [8], new methods are becoming available to accomplish this task. In this study, capacitively-coupled (through clothing) sensors were evaluated against this standard to determine if the R-R interbeat intervals of the two methods were “the same” or not. The test results indicate that, relative to the ECG contact electrode, the CCNE sensors work for determining R-R interbeat intervals reliably. The statistical analysis of the test results between the CCNE and the contact electrode give the following conclusions:

1) The CCNE method gives "unbiased" estimates (116 out of 117 difference signals gave "unbiased" estimates).

2) The CCNE method gives estimates "close" to the ECG measurements (30 out of 39 test subjects had all CCNE intervals within 14 milliseconds of the ECG intervals).

3) The CCNE difference signals give statistically "similar" results within each test subject (37 out of 39 test subjects had statistically similar results).

4) Females showed more variability than males for each weight class.

5) Males and females in weight class 5 had the largest measures of variability.

Part of the pilot study was to choose a location on the body for the sensors that would provide a reasonably good signal and be consistent across the test population. The transverse plane location (see Figure 4) that was chosen worked well for most of the test subjects. As indicated by the statistics, the larger weight group (group 5 for males and females) had the greatest variability. This can be explained in terms of the placement of the sensors relative to the transverse plane at the sternum. The placement in weight class 5 for females and males was the hardest placement due to anatomical differences in the larger stature of this group of test subjects—large body types for the men and fairly large breast sizes for the women. Since the sensors were held onto the test subject with a Velcro strap, these anatomical differences provided more possibility of incorrect placement or misalignment of the sensors compared to the other weight classes. Part of this study was to identify these problems and see how susceptible this technology is to factors created by the difference in body types. As a result of this study, many problems have been identified and corrected in the latest version of the sensor. A new clinical study of the technology with these corrections will be undertaken to see if these problems have been eliminated.

This study has shown that ECG interbeat intervals can be obtained through clothing reliably using the new noncontact capacitively couple electrodes. More work is required to study the fidelity of the waveforms to each other to determine if clinical diagnosis is possible using these electrodes.

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